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EXAMINER	
MYERS,C	
ART UNIT	**PAPER NUMBER**
1655	10

DATE MAILED: 09/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/250,883	Russell et al
Examiner	**Group Art Unit**
Carla Myers	1655

☒ Responsive to communication(s) filed on *Jun 26, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *9, 13-20, and 24* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *9, 13-20, and 24* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. This action is in response to Paper No. 9, filed June 26, 2000. Applicants arguments have been fully considered but are not persuasive to overcome all grounds of rejection. Any rejections not reiterated herein are withdrawn. This action contains new grounds of rejection and is made non-final.

2. The following constitutes new grounds of rejection:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9, 13-20 and 24 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific or well-established utility.

The claims are drawn to polynucleotides having at least 70% identity with any one of SEQ ID NO: 1-14. The claimed polynucleotides are not supported by either a specific and substantial asserted utility or a well-established utility. The specification fails to provide objective evidence of any activity for the claimed polynucleotides or to show that polynucleotides having the stated consensus sequence of SEQ ID NO: 14 even exist. The specification teaches that a consensus sequence derived from SEQ ID NO: 1-13 hybridizes to ESTs in 27% of breast tissue samples, whereas the consensus sequence only hybridizes to ESTs in 3.4% of non-breast tissue samples. Based on this information, the specification concludes that the individual sequence fragments of SEQ ID NO: 1-13 and the consensus sequence of SEQ ID NO: 14 are useful in "detecting, diagnosing, staging, monitoring, prognosticating, preventing or treating or determining the

predisposition to, disease and conditions of the breast, such as breast cancer" (see page 10 of the specification). However, the specification provides absolutely no evidence that the sequences of SEQ ID NO: 1-14 are correlated with any type of disease or condition of the breast. There is no information provided in the specification regarding the level of expression of SEQ ID NO: 1-14 in any type of diseased breast tissue. The finding that mRNAs which hybridize to SEQ ID NO: 14 are more prevalent in breast tissue than in normal tissue does not indicate that such sequences are associated with diseases or conditions of the breast. Furthermore, the finding that mRNAs which hybridize to SEQ ID NO: 14 are more prevalent in breast tissue rather than normal tissues does not indicate that mRNAs which hybridize to any one of SEQ ID NO: 1-13 are also more prevalent in breast tissue because there is no evidence concerning the hybridization properties of the individual nucleotide fragments. Furthermore, the claims as written are inclusive of all nucleic acids having 70% identity with SEQ ID NO: 1-14. The specification does not disclose a single nucleic acid having 70% identity with any of SEQ ID NO: 1-14 and does not exemplify any conditions or diseases associated with any species in the genus of nucleic acids having 70% identity with SEQ ID NO: 1-14. The specification suggests that the claimed polynucleotides could be used for therapeutic purposes. Clearly, further research would be required to identify a disease for which the protein encoded by SEQ ID NO: 1-14 is involved and for which treatment with SEQ ID NO: 1-14 or any nucleic acid having 70% identity with SEQ ID NO: 1-14 would be effective or for which detection of SEQ ID NO: 1-14 expression would be informative. As stated in Brenner v. Manson, 383 U.S. 519 535-536, 148 USPQ 689, 696 (1966) " a patent is not a

hunting license. It is not a reward for the search, but compensation for its successful conclusion". Support for an asserted utility that is specific and substantial would require, for example, a showing of a particular function for an encoded polypeptide. Merely identifying and studying the properties of a polypeptide or the diseases in which a polypeptide or polynucleotide may be involved does not constitute a "real world" context of use. Moreover, the use of the claimed polynucleotides to detect breast tissue is considered to be a general use, rather than a specific use since tissue specific expression is a characteristic of a large genus of nucleic acids. Accordingly, the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility. Applicants attention is drawn to the Revised Interim Utility Guidelines set forth in the Federal Register, December 21, 1999. Vol. 64, No. 244, pages 71427-71440.

3. Claims 9, 13-20 and 24 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, or credible asserted utility or well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Furthermore, with respect to the breadth of the claims, it is noted that the claims are drawn to polynucleotides having at least 70% identity with SEQ ID NO: 1-14. The claims further encompass polynucleotides which encode for at least one epitope. It is also noted that the claims have been amended to delete the reference to a "BS203" polynucleotide. However, the claimed polynucleotides have been defined in the specification only in terms of the fact that they are BS203 polynucleotides or comprise fragments of BS203 polynucleotides. Accordingly, deleting

the term "BS203" from the claims does not change the definition of SEQ ID NO: 1-14 provided in the specification. The specification discloses a single polynucleotide having the sequence of SEQ ID NO: 14 wherein said polynucleotide was constructed by overlapping contiguous clones isolated from breast tissue wherein said clones consist of the sequences of SEQ ID NO: 1-13. While the specification has constructed a single polynucleotide expressed in human breast tissue by determining the consensus sequence of overlapping cDNA clones, the specification has not identified any variants or homologs of this polynucleotide. It is unclear from the specification as to what would be considered to be the functional and/or structural properties of a polynucleotide consisting of SEQ ID NO: 1-14 or a polynucleotide having 70% identity with SEQ ID NO: 1-14. No specific guidance has been provided in the specification as to how to reasonably isolate additional BS203 polynucleotides without undue experimentation. It is well established that to claim a chemical compound, such as a polynucleotide, the inventor must be able to define the compound so as to distinguish the compound from other materials and the inventor must clearly define the compound in terms of structure and/or function (e.g. nucleic acid sequence, length of nucleic acid, specific functional activity of nucleic acid) so as to provide a permanent and definite idea of the complete and operative invention. Without a clear and fixed definition of the claimed invention, the skilled artisan cannot make and use that invention without undue experimentation. In the instant case, the specification has not clearly defined the structural and functional activities of what is intended to be encompassed by molecules having the sequence of SEQ ID NO: 1-14. Secondly, the specification has identified only 14 fragments of a BS203 polynucleotide, yet the

claims are drawn to nucleic acids having at least 70% identity with SEQ ID NO: 1-14. Therefore, the claims encompass a phenomenally large genus of nucleic acids, yet the specification teaches only 14 members of this genus. The specification teaches that the disclosed nucleic acids are useful for the specific detection of BS203 or for the diagnosis and detection of breast cancer (see pages 9-10). Yet, the specification has not exemplified any probes or primers having only 70% identity with SEQ ID NO: 1-14 which have been successfully employed to detect BS203 or to detect diseases of the breast. It is highly unpredictable as to whether nucleic acids having such low levels of sequence identity with SEQ ID NO: 1-14 would be useful for specific hybridization to BS203. No guidance is provided in the specification as to what level of sequence identity is required for the claimed nucleic acids to be functional for the hybridization to and detection of BS203 or for the detection or diagnosis of breast cancer. Because the claims do not require that the claimed polynucleotides have at least 70% identity over the full length of SEQ ID NO: 1-14, the claims also include polynucleotides of any minimal length, including 2 or 3 nucleotides, etc. There is no specific guidance provided in the specification for using small fragments of the disclosed polynucleotides as primers or probes to specifically detect breast tissue specific genes. Thirdly, the claims as written are inclusive of nucleic acids comprising flanking genomic sequences and nucleic acids which consist of the full length BS203 genes. However, the specification does not provide an example of the genomic structure of BS203. There is no disclosure as to what would be the length of the complete gene, of sequences present in the 5' regulatory region of the gene or intronic sequences of the gene. There is also no specific

guidance provided in the specification as to how to reasonable isolate the fully length BS203 gene without undue experimentation. Lastly, claims 15 and 24 are directed to polynucleotides which comprise a sequence encoding at least one epitope. Yet, the specification does not identify any epitopes and no guidance is provided as to how one of skill in the art would select appropriate fragments of a protein which function as an epitope. In view of the lack of disclosure in the specification as to portions of the SEQ ID NO: 1-14 which would encode for epitopes and in view of the lack of guidance provided in the specification as to how to select nucleic acids which would encode suitable epitopes, undue experimentation would be required for one of skill in the art to successfully identify nucleic acids that could be used to synthesize BS203 epitopes. Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the specification has identified 13 fragments of a BS203 nucleic acid and one consensus BS203 nucleic acid (i.e., SEQ ID NO: 14), yet the scope of the claims encompasses a huge genus of nucleic acids having 70-100% identity with SEQ ID NO 1-14 and fragments of any

length of said nucleic acids. Thereby, the scope of the claims do not bear a reasonable correlation to the scope of enablement provided by the specification and undue experimentation would be required to practice the full scope of the claims because this would require randomly analyzing this huge genus of nucleic acids to identify which members may hybridize to BS203 and would be useful for the detection of BS203 or for the detection of breast cancer or which would encode for epitopes of BS203 protein. Such random, trial by error experimentation is considered to be undue. In summary, in view of the high level of unpredictability in the art of identifying new genes and primers and probes and in view of the lack of guidance and information provided in the specification as to what constitutes a BS203 polynucleotide and as to how to distinguish this polynucleotide from other polynucleotides and as to how to isolate other BS203 polynucleotides from other organisms, and because the specification has not exemplified or provided sufficient guidance as to how to use a representative number of BS203 polynucleotides having 50% identity with SEQ ID NO: 1-14 or fragments thereof or sequences having any level of complementary thereto, undue experimentation would be required to practice the invention as it is broadly claimed.

In the response filed June 26, 2000, Applicants argued that the sequences are members of a RING finger family. It is argued that domains within SEQ ID NO: 17 are similar to a region with a ring finger motif. However, the specification as originally filed does not characterize the claimed nucleic acids as encoding a RING finger protein. Therefore, the specification as originally filed did not teach one of skill in the art to select and use variants having 70% identity with SEQ

ID NO: 1-14 based on said molecules having the property of encoding a RING finger protein. Furthermore, the fact that the claimed nucleic acids encode for proteins having domains known to be present in RING finger proteins does not indicate that the claimed nucleic acids encode for proteins having the same functional properties as the RING finger proteins in the prior art. No evidence has been provided in the specification to show that any of the claimed nucleic acids or nucleic acids having 70% identity thereto encode for proteins having any functional activity and particularly no evidence has been provided to show that the claimed nucleic acids encode for proteins having the functional activity of a RING finger protein. Identifying domains within a new protein which are conserved with other known proteins, does not indicate what specific function the new protein might have. Applicants argue that the prior art teaches how to search databases for hydrophobicity and hydrophilicity values and thereby one of skill in the art would be able to identify epitopes. However, the specification has not demonstrated that SEQ ID NO: 14 actually encodes for a naturally occurring protein, let alone that SEQ ID NO: 1-13 or sequences having 70% identity thereto encode for proteins having epitopes. If epitopes could be identified within these sequences, one of skill in the art would not know how to use the proteins encoding epitopes because no activity has been established for the protein nor has expression of the protein been associated with any diseases or conditions.

4. Claims 9, 13-20 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides wherein said polynucleotide has at least 70% identity with SEQ ID NO: 1-14.The claims as broadly written include nucleic acids in which sequences are present flanking SEQ ID NO: 1-14. The broadest reasonable interpretation of the claims indicates that the claims are inclusive of BS203 genes and BS203 genomic sequences. However, the specification does not teach any full length BS203 genes or any BS203 genomic sequences. In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only 14 members of the broadly claimed genus have been defined by their structure, i.e. SEQ ID NO: 1-14. No genomic sequences flanking SEQ ID NO: 14 have been defined. There is no evidence in

the specification to indicate that any of the sequences of SEQ ID NO: 1-13 consist of full open reading frames or consist of sequences which span more than one exon. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, chromosomal map position, biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of the polynucleotides. While at the time of filing applicants were in possession of polynucleotides consisting of SEQ ID NO: 1-14, the specification provides no information regarding genomic sequences surrounding the sequences of SEQ ID NO: 1-14. Furthermore, the specification does not identify any additional BS203 nucleic acids other than the consensus sequence of SEQ ID NO: 14. With respect to claim, the specification does not identify any epitopes of BS203. In fact, the specification does not provide any specific evidence of a BS203 protein and clearly does not define any epitopes of the putative protein. Furthermore, the specification does not exemplify any molecules having 70%, etc. identity with SEQ ID NO: 1-14. A representative number of species encompassed by the genus of polynucleotides having at least 70% identity with SEQ ID NO: 1-14 are not disclosed in the specification. The limited information provided in the specification is not deemed sufficient to reasonably convey to one of skill in the art that Applicants were in possession of full length BS203 genes, genomic BS203 nucleic acids, BS203 nucleic acids other than that of SEQ ID NO: 14, polynucleotides encoding BS203 epitopes or the broad genus of nucleic acids having at least 70% identity with SEQ ID NO: 1-14. Therefore, the written description requirement has not been satisfied for the claims as

they are broadly written. Applicants attention is drawn to the Revised Interim Guidelines for Written Description set forth in the Federal Register, December 21, 1999. Vol. 64, No. 244, pages 71427-71440.

In the response filed June 26, 2000, Applicants assert that the rejection should be withdrawn because Applicants have amended the claims to delete the "BS203" language and to recite that the claimed polynucleotide has 70% identity rather than 50% identity with SEQ ID NO: 1-14. However, it is not clear as to how deleting the term "BS203" obviates the written description requirements. The claimed nucleic acids have been described and characterized in the specification only in terms of being BS203 nucleic acids or comprising portions of a BS203 nucleic acid. No other description or characterization of the claimed nucleic acids is provided in the specification. Amendment of the claims to recite 70% identity in place of 50% identity does not overcome the written description rejection in view of the fact that the specification has identified one molecule, SEQ ID NO: 14, and 13 fragments that are assembled to obtain SEQ ID NO: 14. No nucleic acid molecules having 70%-99% identity with SEQ ID NO: 1-14 have been described in the specification. Accordingly, a representative number of species encompassed by the genus of polynucleotides having at least 70% identity with SEQ ID NO: 1-14 are not disclosed in the specification. In addition, the amendment does not obviate the rejection as it applies to the fact that the claims are inclusive of genomic sequences. The specification has not provided evidence that SEQ ID NO: 1-13 encode for full length open reading frames or for sequences spanning more than one exon. Polynucleotides having 70% identity with exon

fragments are inclusive of polynucleotides having flanking sequences in addition to those sequences with identity to SEQ ID NO: 1-13. There is no disclosure in the specification of flanking intron sequences or flanking 5' or 3' untranslated sequences. Therefore, the rejection is maintained.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Inoue (Proceedings of the National Academy of Sciences (December 1993) 90: 11117-11121).

Inoue (Figure 2) teaches polynucleotides encoding the estrogen-responsive finger (efp) gene wherein the efp polynucleotides share at least 70% identity with a fragment of SEQ ID NO: 14. Portions of the efp gene share 70% identity with instant SEQ ID NO: 1. The polynucleotides of Inoue are considered to comprise an epitope because essentially any fragment of a nucleic acid is expected to encode for a peptide which will elicit some level of an immune response in some organism. Inoue (page 11117) teaches cloning the efp polynucleotides (i.e. λC3) into an expression vector, transfecting host COS-7 cells with the resulting recombinant expression vector and methods for synthesizing efp proteins using said transfected host cells.

In the response filed June 26, 2000, Applicants state that this rejection has been obviated by the amendment to the claims to delete the "fragment" language. However, the claims require

that the protein comprises an amino acid sequence having 70% identity with SEQ ID NO: 17-21. The claims do not require that the % identity is determined over the full length of SEQ ID NO: 17-21. Accordingly, the claims encompass proteins comprising an amino acid sequence that has 70% identity over some portion of SEQ ID NO: 17-21. Therefore, the rejection is maintained over claim 24 because the claim is inclusive of methods of making a protein wherein the protein comprises a region having at least 70% identity with SEQ ID NO: 17-21 and thereby encompasses the method of making the efp protein disclosed by Inoue.

6. Claims 9, 13-15, 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al (GenBank Accession No. R77167 or H15926).

The polynucleotide of GenBank Accession No. H15926 shares 98% identity with nucleotides 54-249 of instant SEQ ID NO: 14 and the polynucleotide of GenBank Accession No. R77167 shares 96.2% identity with nucleotides 660-1095 of instant SEQ ID NO: 14. The polynucleotides of Hillier are also considered to comprise an epitope because essentially any fragment of a nucleic acid is expected to encode for a peptide which will elicit some level of an immune response in some organism. Accordingly, the polynucleotides of Hillier share at least 70% identity with SEQ ID NO: 14.

In the response filed June 26, 2000, Applicants state that this rejection has been obviated by the amendment to the claims to delete the "fragment" language. However, the claims require only that the polynucleotide has at least 70% identity with SEQ ID NO: 14. The claims do not require that the % identity is determined over the full length of SEQ ID NO: 14. Accordingly, the

claims encompass polynucleotides having at least 70% identity with portions of SEQ ID NO: 14. Thereby, the rejection is maintained because the full length molecules of H15926 and R77167 have at least 70% identity with SEQ ID NO: 14.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al (GenBank Accession No. R77167 or H15926) in view of Linksens.

Hillier teaches the polynucleotide of GenBank Accession No. H15926 shares 98% identity with nucleotides 54-249 of instant SEQ ID NO: 14 and the polynucleotide of GenBank Accession No. R77167 shares 96.2% identity with nucleotides 660-1095 of instant SEQ ID NO: 14. The polynucleotides of Hillier are also considered to comprise an epitope because essentially any fragment of a nucleic acid is expected to encode for a peptide which will elicit some level of an immune response in some organism. Hillier does not teach attaching the isolated polynucleotides

to a solid support. Linskens (col. 15-16) teaches that probes comprising EST sequences may be immobilized onto a solid support in order to facilitate hybridization methods and to allow for the detection of cells expressing nucleic acids complementary to said probes. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have immobilized the EST polynucleotides of Hillier onto a solid support as taught by Linskens in order to have provided a simple and effective means for detecting expression of the isolated polynucleotides in cell samples.

In the response filed June 26, 2000, Applicants traversed this rejection for the same reasons set forth in paragraph 8 above. Accordingly, the response to those arguments applies equally to the present grounds of rejection.

8. Claims 19, 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al (GenBank Accession No. R77167 or H15926) in view of Inoue.

Hillier teaches the polynucleotide of GenBank Accession No. H15926 shares 98% identity with nucleotides 54-249 of instant SEQ ID NO: 14 and the polynucleotide of GenBank Accession No. R77167 shares 96.2% identity with nucleotides 660-1095 of instant SEQ ID NO: 14. The polynucleotides of Hillier are also considered to comprise an epitope because essentially any fragment of a nucleic acid is expected to encode for a peptide which will elicit some level of an immune response in some organism. Hillier does not teach cloning the polynucleotides into expression vectors, transforming host cells with the resulting vectors or expressing polypeptides using the transformed host cells. However, Inoue teaches cloning polynucleotides, particularly

polynucleotides encoding efp, into expression vectors, transforming host cells with the resulting recombinant vectors and expressing polypeptides encoded by the polynucleotides using the transformed host cells (see pages 11119-111120). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have cloned the polynucleotides of Hillier into expression vectors, to have transformed host cells with the resulting vectors and to have used the transformed cells to express polypeptides in order to have provided an effective means for synthesizing polypeptides encoded by the isolated polynucleotides which would have allowed for the further characterization of the functional properties of the isolated polynucleotides and the products encoded by the isolated polynucleotides.

In the response filed June 26, 2000, Applicants traversed this rejection for the same reasons set forth in paragraph 8 above. Accordingly, the response to those arguments applies equally to the present grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
September 7, 2000

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER